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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MYERS, CARLA J	
ART UNIT	**PAPER NUMBER**
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,213	PRICE, SUZANNE MARGARET	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *10,11 and 20-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 12-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 August 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/22/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I and the species of enzymatic treatment in the reply filed on March 12, 2007 is acknowledged. The traversal is on the ground(s) that invention I and II are not independent and distinct because they share the same inventive concept of a method for analyzing a nucleic acid sample obtained from a site comprising the step of pretreating the sample to remove or inactivate contaminating nucleic acids. Applicants further assert that undue burden would not be required to examine inventions I and II together because the inventions share the same inventive concept. This is not found persuasive because while invention I is drawn to a method of analyzing a nucleic acid comprising pretreating a nucleic acid sample to remove or inactivate contaminating nucleic acids, invention II is drawn to a kit. The intended use of the kit does not carry weight with respect to the novelty or obviousness of the claimed kits. Therefore, a search for invention I and II is not co-extensive with one another and it is maintained that undue burden would be required to examine these groups together. Further, A 371 application is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, the linking technical feature of a means for removing a nucleic acid contaminant was known in the art at the time the invention was made and thereby does not constitute a contribution

over the prior art. For example, Walker (EP 0585660; cited in the IDS) teaches the use of exonucleases to remove contaminating nucleic acids from a reaction (see pages 5-8). Sillekens (WO 00/00638; cited in the IDS) discloses kits and methods of using kits wherein the kits contain a nucleic acid probe that hybridizes to a transcribable non-target sequence (see pages 7-8). It is a property of this probe that it can bind to a nucleic acid contaminant and thereby aid in its removal. Thus, there is no special technical feature linking the recited groups, as would be necessary to fulfill the requirement for unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-22 are pending. Claims 10-11 and 20-22 are withdrawn from consideration as being drawn to a non-elected invention. Claims 1-9 and 12-19 have been examined herein. It is noted that claim 8 has been examined only to the extent that the claim reads on the elected invention of methods wherein the pretreatment is an enzymatic pretreatment.

Claim Objections

3. Claim 9 is objected to because of the following informalities:

Claim 9 recites "and/or **25** endonucleases" whereas it appears the claim should recite "and/or endonucleases."

4. Claim 19 is objected to because a claim to a method does not properly depend from a step recited in another claim to a method. As stated in MPEP 608.01(n), "The test as to whether a claim is a proper dependent claim is that it shall include every limitation of the claim from which it depends (35 U.S.C. 112, fourth paragraph) or in other words that

it shall not conceivably be infringed by anything which would not also infringe the basic claim... On the other hand, if claim 1 recites a method of making a specified product, a claim to the product set forth in claim 1 would not be a proper dependent claim since it is conceivable that the product claim can be infringed without infringing the base method claim if the product can be made by a method other than that recited in the base method claim." In the present situation, claim 19 refers to only the pre-treatment steps of claim 7, rather than the complete method of claim 7. Thereby, claim 17 does not include every limitation of the claim from which it depends (i.e., claim 7).

5. Claim 19 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may refer to more than one claim only in the alternative. See MPEP § 608.01(i) and (n). In the present situation, claim 19 depends from both claims 17 and 7. In the interest of compact prosecution, claim 19 has been examined herein. However, in response to this Office action, claim 19 must be amended so that it depends from only one claim or depends from multiple claims in the alternative.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 and 12-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9 and 12-19 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap

between the steps. See MPEP § 2172.01. The omitted steps are the steps of analyzing the nucleic acid. That is, the claims are drawn to method for analyzing a nucleic acid sample. However, the claims recite only a step of pretreating a sample. The claims do not recite any steps of analyzing a nucleic acid sample.

Claims 3, 4 and 14 are indefinite over the recitation of "particularly well adapted for amplification via PCR." This phrase is not clearly defined in the specification and there is no art recognized definition for this phrase. Further, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. It is unclear as to whether unclear as to whether a contaminating nucleic acid that is particularly adapted for amplification is distinct from a nucleic acid that is merely adapted for amplification or from any other contaminating nucleic acid. Accordingly, one of skill in the art would not be able to determine the meets and bounds of the claimed subject matter.

Claims 8 and 9 are indefinite over the recitation of "selected from the group comprising" because the claim recites an improper format for a Markush group. Claims which recite members of a Markush group must be 'close-ended'. This rejection may be overcome by amendment of the claim to recite "selected from the group consisting of". See MPEP 2173.05(h):. "It is improper to use the term "comprising" instead of "consisting of." Ex parte Dotter, 12 USPQ 382 (Bd. App. 1931).").

Claim 12 is indefinite over the recitation of "wherein the method of analyzing the nucleic acid sample is PCR, mitochondrial DNA sequence...and low copy number PCR.

It is unclear as to how the method of analyzing a nucleic acid sample can comprise each of these methodologies. It appears that the claim should refer to the distinct methods in the alternative. Further, it is unclear as to how this recitation is intended to further limit the claim since the claim does not recite an active process step of performing PCR, or DNA sequencing etc.

Claim 16 is indefinite over the recitation of "nucleic acid is bacteria." While bacteria contains nucleic acids, bacteria is not itself a nucleic acid. Accordingly, it is unclear as to what is intended to be meant by the phrase "nucleic acid is bacteria."

Claims 17-19 are indefinite over the recitations of "the nucleic acid in the cells" because this phrase lacks proper antecedent basis. While the claims previously refer to "cell bound contaminating nucleic acids," the claims do not previously refer to a nucleic acid in a cell.

Claims 18 and 19 are indefinite over the recitation of "the nucleic acid" because it is not clear as to whether this phrase refers to the "contaminating nucleic acid" or to the "nucleic acid in the cells" or the nucleic acid removed from the cells or removed from the sample.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Walker (EP 0585660; cited in the IDS).

Walker teaches a method for analyzing a nucleic acid sample obtained from a site wherein the method comprises: i) pretreating the nucleic acid sample with a single-strand specific exonuclease to remove or inactivate contaminating nucleic acids obtained from the site; and ii) amplifying the pretreated sample to thereby analyze the nucleic acid sample (see, e.g., page 2, lines 24-34 and page 4, lines 43-46). In the method of Walker, the step of treating the nucleic acid sample with a single-strand specific exonuclease constitutes a step of pretreating the sample.

Regarding claim 2, in the method of Walker, the nucleic acid is DNA (see, e.g., page 4, lines 3-15 and Example 2).

Regarding claim 3, the contaminating nucleic acid is considered to be well adapted for amplification via PCR since the contaminating nucleic acid may be amplified and may be the products (amplicons) of previous amplification reactions (see, e.g. page 2, lines 7-13).

Regarding claim 4, Walker teaches that the contaminating nucleic acid may be an amplicon from a previous PCR (see, e.g. page 2, lines 7-13).

Regarding claim 5, the contaminating nucleic acid is considered to be degradation resistant since DNA is substantially more stable than other molecules and is resistant to many enzymes, such as RNases.

Regarding claim 6, the contaminating nucleic acid is considered to be synthetic since nucleic acids that have been synthesized by some process such as an amplification process constitute synthetic nucleic acids.

Regarding claim 7, the method of Walker is one in which the pretreatment preferentially removes or inactivates nucleic acids produced by other amplification processes and thereby removes or inactivates nucleic acids that are free or substantially free of other cell components.

Regarding claims 8 and 9, the pretreatment step of Walker comprises treating the nucleic acid sample using an exonuclease (page 2, lines 24-30).

Regarding claim 12, Walker (page 2, lines 40-53) teaches that following the pretreatment step, the nucleic acid sample may be analyzed by any amplification method, including the method of PCR.

8. Claims 1-3, 5, 6, 8, 9, and 12-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Miwa (U.S. Patent No. 4,514,502).

Miwa teaches a method for analyzing a nucleic acid sample obtained from a site wherein the method comprises: i) pretreating the nucleic acid sample with a RNase to remove or inactivate contaminating nucleic acids obtained from the site; and ii) analyzing the pretreated nucleic acid sample (see, e.g., col. 6, lines 56-68 through col. 7, lines 1-6 and 48-51). In the method of Miwa, the step of treating the nucleic acid sample with RNase constitutes a step of pretreating the sample to remove or inactivate contaminating RNA.

Regarding claim 2, in the method of Walker, the contaminating nucleic acid present in the sample is RNA (see, e.g., col. 6, lines 56-68 through col. 7, lines 1-6).

Regarding claims 3 and 14, the contaminating nucleic acid is considered to be well adapted for amplification since RNA can be readily amplified by reverse transcription.

Regarding claim 5, the contaminating nucleic acid is considered to be degradation resistant since RNA is resistant to many enzymes, such as DNases.

Regarding claim 6, the contaminating nucleic acid is considered to be synthetic since RNA present in a bacterial cell has been synthesized.

Regarding claims 8 and 9, the pretreatment step of Miwa comprises treating the nucleic acid sample using the enzyme RNase (col. 6, lines 68-col. 7., line 1).

Regarding claim 12, it is a property of the resulting nucleic acid that it can be analyzed by any amplification method, including the method of PCR. It is noted that the claim does not in fact require performing an active step of amplifying the isolated nucleic acid.

Regarding claims 13-19, Miwa (col. 6, lines 56-68) teaches that the bacterial cell is first lysed prior to treatment with RNase. Accordingly, the pretreatment steps of Miwa include removing cell bound nucleic acids from a cell by exposing the nucleic acids in the cells using a lysing procedure and then removing the nucleic acids using an RNase pretreatment step.

Regarding claim 15, the contaminating RNA is of bacterial origin since it is present in a bacterial cell.

Regarding claim 16, the bacterial cell has been engineered to carry a multicopy plasmid containing at least one amplicon (see col. 2, lines 22-25; col. 3, lines 3-50; col. 4, lines 38-45).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Carla Myers

Art Unit 1634

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CARLA J. MYERS
PRIMARY EXAMINER